STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION
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August 1, 2014

Dear Interested Party:

Enclosed is the Second Discussion Paper on Regulation 1591, *Medicines and Medical Devices*. Before the issue is presented at the Board's November 18, 2014 Business Taxes Committee meeting, staff would like to invite you to discuss the issue and present any additional suggestions or comments. Accordingly, a second interested parties meeting is scheduled as follows:

August 14, 2014
Room 122 at **10:00 a.m.**
450 N Street, Sacramento, CA

If you would like to participate by teleconference, call 1-888-636-3807 and enter access code 499201. You are also welcome to submit your comments to me at the address or fax number in this letterhead or via email at Susanne.Buehler@boe.ca.gov by September 4, 2014. Copies of the materials you submit may be provided to other interested parties, therefore, ensure your comments do not contain confidential information. Please feel free to publish this information on your website or distribute it to others that may be interested in attending the meeting or presenting their comments.

If you are interested in other Business Taxes Committee topics refer to our webpage at (http://www.boe.ca.gov/meetings/btcommittee.htm) for copies of discussion or issue papers, minutes, a procedures manual, and calendars arranged according to subject matter and by month.

Thank you for your consideration. We look forward to your comments and suggestions. Should you have any questions, please feel free to contact our Business Taxes Committee staff member Michael Patno at 1-916-327-2045, who will be leading the meeting.

Sincerely,

Susanne Buehler

Susanne Buehler, Chief
Tax Policy Division
Sales and Use Tax Department

SB: map

Enclosures

cc: (all with enclosures)
Honorable Jerome E. Horton, Chairman, Fourth District
Honorable Michelle Steel, Vice Chair, Third District
Honorable Betty T. Yee, Member, First District (MIC:71)
Senator George Runner (Ret.), Member, Second District (via email)
Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel

(via email)
Mr. David Hunter, Board Member's Office, Fourth District
Mr. Jaclyn Appleby, Board Member's Office, Fourth District
Mr. Neil Shah, Board Member's Office, Third District
Mr. Tim Treichelt, Board Member's Office, Third District
Mr. Alan LoFaso, Board Member's Office, First District
Ms. Mengjun He, Board Member's Office, First District
Ms. Yvette Stowers, Board Member's Office, First District
Mr. Ramon Salazar, Board Member's Office, First District
Mr. Sean Wallentine, Board Member's Office, Second District
Mr. James Kuhl, Board Member's Office, Second District
Mr. Lee Williams, Board Member's Office, Second District
Mr. Alan Giorgi, Board Member's Office, Second District
Ms. Lynne Kinst, Board Member's Office, Second District
Ms. Tanya Vandrick, Board Member's Office, Second District
Ms. Natasha Ralston Ratcliff, State Controller's Office
Ms. Cynthia Bridges (MIC:73)
Mr. Randy Ferris (MIC:83)
Mr. Jeffrey L. McGuire (MIC:43)
Mr. Jeff Vest (MIC:85)
Mr. Jeff Angeja (MIC:85)
Mr. David Levine (MIC:85)
Mr. Robert Tucker (MIC:82)
Mr. Bradley Heller (MIC:82)
Mr. Scott Claremon (MIC:82)
Mr. Lawrence Mendel (MIC:82)
Mr. Todd Gilman (MIC:70)
Ms. Laureen Simpson (MIC:70)
Mr. Bill Benson (MIC:67)
Mr. Joe Fitz (MIC:67)
Mr. Wayne Mashihara (MIC:46)
Mr. Kevin Hanks (MIC:49)
Ms. Kirsten Stark (MIC:50)
Mr. Clifford Oakes (MIC:50)
Ms. Karina Aguilar (MIC:46)
Mr. Bradley Miller (MIC:92)
Mr. Michael Patno (MIC:50)
Mr. Robert Wilke (MIC:50)

SECOND DISCUSSION PAPER

Proposed Revisions to
Regulation 1591, *Medicines and Medical Devices*

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of "medicines" includes devices implanted to mark the location of a medical condition?

II. Staff Recommendation

Staff recommends amending Regulation 1591, as set forth in Exhibit 1, to:

- Clarify that permanently implanted articles used to mark the location of a medical condition are included in the definition of medicines, with breast tissue markers being an example of such a device.

- Specify that the term, "approved by the U.S. Food and Drug Administration," as it relates to medical devices, means any device for which a premarket notification was cleared by the United States Food and Drug Administration (FDA) or for which an application for premarket approval was approved by the FDA.

- Make non-substantive changes to correct grammatical errors, sentence structure, and inconsistent abbreviations.

III. Other Alternative(s) Considered

Staff held a meeting with interested parties on June 16, 2014, to discuss proposed amendments to Regulation 1591 and the initial discussion paper which provided the background for and explained the amendments. Following the meeting, staff received two submissions from interested parties.

In a June 26, 2014, letter, Mr. Wade Downey and Mr. Roderick Calub of Downey, Smith & Fier (Downey), expressed the opinion that staff's proposed changes do not resolve the confusing structure of Regulation 1591, specifically subdivisions (a)(9)(A), (b), and (c). Downey suggests that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) alone. Therefore, Downey considers any reference to subdivisions (b) and (c) to be irrelevant. (See Exhibit 2.)

Staff also received written comments from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. In his June 26, 2014, letter, Mr. Bholat suggests removing the specific exclusions from subdivision (b)(2) for "Chemoport implantable catheters," "Port-a-Cath systems used for drug infusion purposes," "disposable urethral catheters," and "defibrillator programmers and high voltage stimulators used with an implanted defibrillator." (See Exhibit 3.)

While no specific language was included with either of the submissions, the concerns are addressed in this paper.

SECOND DISCUSSION PAPER

Proposed Revisions to

Regulation 1591, *Medicines and Medical Devices*

IV. Background

Revenue and Taxation Code (RTC) section 6369, as interpreted and implemented by Regulation 1591, provides that the sales or use of medicines are not subject to tax if they are sold or otherwise transferred under specified circumstances. In RTC section 6369, subdivision (b), "medicines" are defined as "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." It further provides that certain items are excluded from the definition of medicines, including "(2) Articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." However, section 6369, subdivision (c), includes additional specific items that are, notwithstanding subdivision (b), considered to be medicines.

Regulation 1591 has been revised over the years to clarify the definition of "medicines," but in general it closely resembles the structure of section 6369. Regulation 1591, subdivision (a)(9) defines "medicines" as follows:

> (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or
>
> (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also include certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (b), in addition to further defining medicines to include preparations and similar substances, includes specific examples in (b)(2) of articles, devices and appliances which are included in the definition of medicines, either generally or for specific uses and others which are excluded from the definition of medicines. Subdivision (c) provides additional exclusions from the definition of medicines except as otherwise provided in subdivision (b).

<u>February 2014 Board Meeting</u>

During the February 2014 Board Meeting, the Members heard a sales and use tax appeal hearing involving breast tissue markers (BTMs). At issue was whether BTMs are medicines and therefore exempt from tax when sold or furnished under the prescribed conditions. The BTMs discussed in the hearing were purchased from an out-of-state vendor. The hospital paid use tax to the Board and then filed claims for refund for the use tax paid.

BTMs are sterile disposable medical devices that are comprised of an introducer needle and applier as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. A doctor inserts the BTM in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by ultrasound, MRI or other imaging methods at a future date.

In a letter from the FDA, Inrad, Inc. received approval to market the devices and was notified the BTMs were deemed Class II medical devices. The BTMs were not subject to the FDA's premarket approval process.

During the hearing, the taxpayer's representative stated that the BTMs are devices that are fully implanted in a person and are approved for marketing by the FDA to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition, and therefore meet the definition of medicine provided in Regulation 1591, subdivision (a)(9)(A). The taxpayer's representative also stated that the BTMs were not the type of article that is excluded from the definition of medicine by subdivision (c)(2).

Conversely, staff stated that a BTM is a "device" which is a type of "article" excluded under subdivision (c). Furthermore, though they are permanently implanted in the human body and aid patients during their medical treatments, BTMs do not assist the functioning of any organ, artery, vein or limb as currently specified by subdivision (b)(2), *Permanently Implanted Articles*. Finally, staff concurred with the Appeals section which contended that BTMs were not "approved" by the FDA. The Board unanimously voted in favor of the claimant and directed the Business Taxes Committee (BTC) staff to clarify the provisions of Regulation 1591 as it relates to Class II medical devices that are fully implanted.

V. Discussion

<u>Permanently implanted devices that mark the location of a medical condition are to be included in the definition of a medicine.</u>

Currently, the definition of a medicine in subdivision (b)(2) includes all permanently implanted articles that assist the functioning of any natural organ, artery, vein or limb and that remain or dissolve in the human body. In the first discussion paper, staff recommended adding language to subdivision (b)(2) to include devices that were "permanently implanted in the human body to mark the location of a medical condition" in the definition of medicine. To provide further clarification, staff recommended adding breast tissue markers as an example of a device permanently implanted to mark the location of a medical condition. No comments or suggested language regarding staff's recommendations were received. Recommendations were supported by interested parties.

In his submission, Mr. Bholat requested further revisions to subdivision (b)(2) to remove specific exclusions for "Chemoport implantable catheters," "Port-a-Cath systems used for drug infusion purposes," "disposable urethral catheters," and "defibrillator programmers and high voltage stimulators used with an implanted defibrillator." Mr. Bholat contends that Chemoport implantable fluid systems and Port-a-Caths may be used for purposes other than drug infusion that would include them in the definition of medicine under subdivision (b)(2) or other subdivisions. He further contends that disposable urethral catheters meet the definition of a prosthetic device and therefore should be included in the definition of medicine under (b)(5). Finally, he contends that, though defibrillator programmers and high voltage stimulators used with an implanted defibrillator are specifically excluded in subdivision (b)(2), they are similar to the components of cochlear implants which are included in the definition of medicine by (b)(2). Mr. Bholat's submission raises issues as to whether certain articles should be defined as medicines either because they meet one of the definitions in subdivision (b) directly, or through analogy to other devices considered to be medicines. The specific devices that Mr. Bholat listed in his submission have been determined not to qualify as a medicine. Therefore, staff does not believe deleting specific exclusions from subdivision (b)(2) regarding the types of devices discussed by Mr. Bholat is appropriate.

<u>Does the definition of medicines contained in subdivision (a)(9)(A) need clarification?</u>

At the first interested parties meeting, it was discussed that the phrase, "unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses" may be confusing as "specifically excluded" and "for all uses" appear to contradict. In their submission, Downey contends that subdivision (a)(9)(A) remains confusing despite staff's revisions, particularly in that it is still not clear to taxpayers that they must look to subdivisions (b) and (c) to determine whether subdivision (a)(9)(A) applies.

Staff agrees with Downey that the revision proposed to the first sentence of subdivision (a)(9)(A), which references subdivision (c), does not provide any added clarity. Therefore, staff decided to instead use the existing language in the first paragraph of subdivision (a)(9)(A). Staff is concerned that revisions to this paragraph will not serve to clarify 1591 and might be interpreted as a change in the definition of medicine. Staff still recommends the inclusion in subdivision (a)(9) of the paragraph regarding FDA approval in order to provide needed clarity. However, Staff has moved that paragraph to the end subdivision (a)(9) to preserve the existing wording of subdivision (a)(9)(A) and (a)(9)(B). Staff has also made minor changes to the paragraph to make the language consistent with the language in (a)(9)(A). Staff proposes the following language to subdivision (a)(9):

> (9) Medicines. "Medicines" means:
>
> (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to

diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

<u>For purposes of subdivision (a)(9)(A), products, "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the FDA or for which an application for premarket approval was approved by the FDA.</u>

As stated previously, Downey contends that subdivision (a)(9)(A) is confusing because it is not clear to taxpayers that they must look to subdivisions (b) and (c) to determine whether subdivision (a)(9)(A) applies. Citing the Board's unanimous decision in February 2014, Downey also contends that the Board's original intent in adding subdivision (a)(9)(A) was to create a separate and distinct definition, and therefore recommends removing the reference to subdivision (c) from subdivision (a)(9)(A) entirely while adding certain restrictions similar to those contained in subdivision (b)(2).

Subdivision (a)(9)(A) was added with the explicit limiting reference to subdivision (c), which, on its face, indicates that the definition in subdivision (a)(9)(A) cannot be applied without reference to subdivision (c), and by reference therein subdivision (b). Removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A), and, therefore, what is included in the definition of medicine. Staff believes this change would not be consistent with the Board's direction to clarify the subdivision. Furthermore, Regulation 1591 was implemented to interpret and apply RTC section 6369, and removing the reference to subdivision (c) would create a new independent definition of medicine which would be inconsistent with RTC section 6369.

Staff believes the recommended amendments sufficiently clarify the definition of a medicine. Downey states that the subdivision should be amended to reflect the explanation from the Initial Discussion Paper, which stated, "if a device does not fall under one of the specific definitions contained in subdivision (b), then it is excluded from the definition of medicines under subdivision (c) without exception, and subdivision (a)(9)(A) does not apply." This explanation is taken out of context in that it was only discussing devices, whereas subdivision (a)(9)(A) applies to all "products." Staff is open to further discussions with interested parties for other possible alternatives to reduce any potential misunderstanding.

Additionally, under Regulation 1591, subdivision (a)(9)(A), one of the requirements for a product to be considered a medicine is that it be approved by the FDA. During the February 2014 hearing, the Board discussed the complicated nature of FDA classification of medical devices, with specific regard to the meaning of the word "approved." Staff recommends adding language to clarify that "approved" by the FDA includes pre-market approval, as well as clearances for pre-market notification. This clarification is supported by interested parties.

Non-substantive changes

Staff recommends minor revisions to address spelling and sentence structure errors noted in Regulation 1591.

VI. Summary

Staff's proposed amendments to Regulation 1591 clarify that the definition of medicine includes permanently implanted devices that mark the location of a medical condition and clarify subdivision (a)(9)(A), with regard to what constitutes "approval" by the FDA. Staff welcomes any comments, suggestions and input from interested parties regarding the issue. Interested parties are encouraged to participate in the August 14, 2014, interested parties meeting. The deadline for interested parties to provide written responses regarding this discussion paper is on September 4, 2014.

Prepared by the Tax Policy Division, Sales and Use Tax Department

Current as of 08/01/2014

§ 1591. Medicines and Medical Devices.

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, and also includes “clinic” as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that “health facility” means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that “clinic” means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an~~in~~ incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or

contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of Section 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) Pharmacy. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of Section 4037 of the Business and Professions Code.

(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of

California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~ United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

For purposes of subdivision (a)(9)(A), products, "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the FDA or for which an application for premarket approval was approved by the FDA.

(b) "Medicines." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids,

vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb or mark the location of a medical condition, and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369(c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthotic Devices. Orthotic devices and their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic

devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of Paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

“Custom-made biomechanical foot orthosis” do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) Prosthetic Devices. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under

one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuffs, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as medicines include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) Drug Infusion Devices. Programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from the Definition of “Medicines.”

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines . Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).

(d) Application of Tax - In General

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a

human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) Specific Tax Applications.

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) Health Facility. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) Antimicrobial Agents Used by Hospital Personnel. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) Vitamins, Minerals, Herbs, and Other Such Supplements. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) ~~of Regulation 1591~~.

(8) Diagnostic Substances, Test Kits, and Equipment. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (-“in vitro”) in an artificial environment. They are not administered in the living body (-“in vivo”). As the substances are not

applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) Records.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "Double Deduction" Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

Note: Text is from the website of the Office of Administrative Law as of 5/14/14. History was removed for ease of review.

DOWNEY·SMITH·FIER
STATE & LOCAL TAX

June 26, 2014

Susanne Buehler
Chief, Tax Policy Division
Sales and Use Tax Department
State Board of Equalization
450 M. Street
Sacramento, CA 94279-0092

Re: Suggestions on Proposed Regulation 1591, *Medicines and Medical Devices*

Thank you for this opportunity to participate in the Interested Party Meeting ("IPM") and the process for the Board of Equalization to revise Regulation 1591, Medicines and Medical Devices to clarify the meaning of subsection (a)(9)(A) and U.S. Food and Drug Administration ("FDA") approval. We appreciate the efforts of audit staff in preparing the initial discussion paper and proposed language to specifically address Subsection (a)(9)(A) and tissue markers as exempt medicines.

Our goal in participating in this process is to ensure that the changes and revisions not only address tissue markers, but also clarify the confusion and challenges that industry faces when determining if an exemption exists under (a)(9)(A). It is important that the revised Regulation be clear as to the requirements of exemption and that taxpayers can administer them as technology and medical practices continue to advance. Our comments are not directed toward any specific product or with the intent to expand the exemption for medicines.

As background, Downey, Smith and Fier serves a significant number of hospitals, medical centers, medical groups, medical product manufacturers and medical supply resellers. We consult with clients on both sides of the procurement process, whether it be vendors trying to determine product taxability or a hospital trying to determine if they should pay tax as billed by a vendor or if they are required to self-assessed use tax. Finally, we were directly involved in

and represented the taxpayer in the appeals decision exempting tissue markers that results in the Board Member's directive to initiate this process.

There were two distinct issues involved in the appeal case:

1) Does, "Approved by the U.S. Food and Drug Administration" only apply to Class III Medical Devices as assert by Audit Staff; and
2) Does or should, 1591(a)(9)(A) create a separate and distinct exemption for products fully implanted or injected in the human body or is exemption contingent on a product being otherwise qualified under subsection (b)?

As to point 1, we believe that staff's proposed language adequately clarifies FDA approval. The proposed language addresses the discussion during the appeals process and is consistent with the Board decision, that is, FDA approval is not limited to a class of product and includes not only premarket approval but also premarket notification or the 510(k) process relying on a substantial equivalent.

Point 2 is a much more important question to this process and in our opinion causes the most confusion and incorrect application of tax by taxpayers, auditors and practitioners when determining taxability of medical products. The current proposed changes, moving the little (c) exclusion from the beginning of the paragraph to the end, does little, if anything, to clarify how subsections (a)(9)(A) applies or does not apply to fully implanted or injected products. The changes also do not clarify or explain the purpose of exempting an implant for all uses (medical v. cosmetic).

As subsection (a)(9)(A) currently reads, Any products fully implanted and injected in the human body subject to the FDA requirement is a medicine (with exception). However, only after migrating through the series of subsection exclusions in (c) and (b), does a taxpayer learn that a fully implanted product used to diagnose a disease is not really exempt because it is not covered in subsection (b). And, you only reach this conclusion after you recognize that subsection (c) actually excludes all products, unless otherwise provided in (b). And, subsection (b)(2) actually only applies to implants that replace or assist a body function. If you're confused, this is exactly how taxpayer's feel trying to navigate this Regulation.

So, how do we fix this? We will try to be specific, but we realized that none of the current language of (a)(9)(A) is consistent with the staff's interpretation of the intent of this section. I quote from the Issue paper, "if a device does not fall under one of the specific definitions

contained in subdivision (b), then it is excluded from the definition of medicines under subdivision (c) without exception, and subdivision (a)(9)(A) does not apply". If this is the Board's intent, then (a)(9)(A) should be amended to state exactly that. However, we have difficulty believing that this is the clarification that the Board Members are seeking especially since they unanimously decided something contrary. Simply, the Board decided that an item fully implanted and approved by the FDA for a medical purpose is exempt.

Overall, it is our opinion, that any product that is fully implanted or injected into a patient for a medical purpose should be exempt based on the plain language of subsection (a)(9)(A). Any reference to subsections (c) or (b) is not relevant. This would be consistent with the unanimously decision by the Board involving tissue markers. It would also be consistent with the Board's 2006 action when they adopted (a)(9)(A) and exempted fully implanted cosmetic products not meeting the specific requirement of subsection (b). Under this approach, staff may want to include a permanent requirement consistent with the requirements for other exempt implants that assist or replace a body function.

This would provide taxpayer's with clear guidance, create a regulation that will withstand the advances in medicine, be consistent with current believes that implants are exempt and specifically address the Board's decision related to implanted tissue markers.

Thank you for your consideration.

Sincerely,

Wade M. Downey
Partner
Downey, Smith & Fier

Roderick Calub
Healthcare, Senior Manager
Downey, Smith & Fier

Cc: Lyle Downey, Partner – Downey, Smith & Fier
Jim Fier, Partner – Downey, Smith & Fier

Patno, Michael

From: Jacob Bholat <jbholat@equityrs.com>
Sent: Thursday, June 26, 2014 9:43 AM
To: Patno, Michael
Cc: 'Farah Mohamedy'; Rrodriguez@equityrs.com
Subject: Interested Parties Discussion - Regulation 1591
Attachments: ERS Interest Parties Letter Regulation 1591 June 2014.pdf; June 2014 Interested parties Letter 1591.pdf

Hi Michael,

Please incorporate our attached response/request for revisions into the Interested Parties Discussion related to upcoming changes to Regulation 1591. Please also confirm the receipt of this email along with the date of the next call, which is scheduled for August 14th at 10 AM.

Thank you,

Jacob Bholat
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Equity Recovery Solutions
State and Local Tax

State Board of Equalization
Interested Parties – Regulation 1591 Revisions
Susanne Buehler
Chief, Tax Policy Division
Sales and Use Tax Department

Ms. Buehler,

We have reviewed the Interested Parties letter dated on June 6, 2014, along with the Discussion Paper related to the proposed revisions to Regulation 1591, Medicines and Medical Devices. We find that the regulation revisions do not address a conflict that directly impacts several of our clients.

Section (a)(9)(A) provides a broadened exemption of implants and specifically excludes items covered under subdivision (c). Subdivision (b)(2) lists additional implanted items that are excluded by the Regulation, which are mostly temporary in nature. While we understand the exclusion of temporary implants and the long standing history of their treatment, the language under Subdivision (b)(2) exclude items that would 1) qualify for permanent use (intended for more than 6 months), 2) qualify as exempt under other parts of Regulation 1591 or 3) may qualify as external related components of permanently implanted items.

1. Chemoport implantable fluid systems and Port-a-Cath system" – based on public information these types of devices have many uses which would qualify under the "diagnosis, cure, mitigation, treatment or prevention of disease" as defined by Regulation 1591. These items generally are intended to remain implanted in the patient for more than six months.

   Below you will find a partial list of common uses *(website: http://en.wikipedia.org/wiki/Port_(medical)).* ***These items should be exempt as permanent implants that qualify under Regulation 1591. These devices would be orthotic in nature as they support the blood vessel system for patients who require long term care.***

   - To deliver total parenteral nutrition in those unable to take (adequate) food orally for a long period of time
   - To deliver chemotherapy to cancer patients who must undergo treatment frequently. Chemotherapy is often toxic, and can damage skin and muscle tissue, and therefore should not be delivered through these tissues. Portacaths provide a solution, delivering drugs quickly and efficiently through the entire body via the circulatory system
   - To deliver coagulation factors in patients with severe hemophilia
   - To withdraw (and/or return) blood to the body in patients who require frequent blood tests, and in hemodialysis patients

- To deliver antibiotics to patients requiring them for a long time or frequently, such as those with cystic fibrosis and bronchiectasis
- Delivering medications to patients with immune disorders
- For treating alpha 1-antitrypsin deficiency with replacement therapy
- For delivering radiopaque contrast agents, which enhance contrast in CT imaging
- To fill or withdraw fluid from the Lap-Band or Realize gastric bands used in Bariatric surgeries
- To administer analgesics to patients with chronic pain, such as cancer patients and those with sickle-cell disease

2. Disposable urethral catheters – while these items will likely not qualify under the permanent implant section of Regulation 1591, they would qualify under Subdivision (b)(5), Prosthetic Devices, as they provide drainage through a natural opening. ***These items should be exempt as prosthetic devices that qualify under Regulation 1591.***

3. Defibrillator programmers and high voltage stimulator used with implanted defibrillator – this direct exclusion conflicts with the treatment of external, fully worn components of an implanted device, as defined by the treatment of cochlear implant components. ***These items would be exempt as permanent implants that qualify under Regulation 1591, if they are fully worn and directly related to a permanent implant (this would need to be determined by the individual product, as they vary in function and structure.***

We respectfully request that BOE Staff remove these sections/sentences from Regulation 1591 (b)(2) as they create uncertainty and inconsistent treatment to medical products by Audit staff and also provide confusion for taxpayers.

Please feel free to contact our firm, if you require any additional information.

Sincerely

Jacob Bholat
Partner
Equity Recovery Solutions, Inc